

DEPARTMENT OF MOLECULAR AND CELLULAR BIOLOGY
HARVARD UNIVERSITY

16 Divinity Avenue
Cambridge, Massachusetts 02738



Tel: (617) 496-3757
Fax: (617) 496-3763

3104 '99 APR -5 AM 56

March 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Subject: FDA-Docket No. 98N- 1265

To whom it may concern:

I have Celiac Disease, a non-contagious autoimmune disorder that causes me to become ill if I eat anything containing or derived from wheat, oats, barley, rye or malt.

Many over-the-counter and prescription medications contain ingredients which are harmful to me, including excipients, such as stabilizers, preservatives, colorings, flavorings, sweeteners, binders, dilutants, disintegrants, lubricants, coatings, additives and inert agents. If I need an over-the-counter or prescription medication, I must do extensive research to see if it contains anything harmful to me. Many times there isn't a product available commercially, and so I have to have a product custom made. Stokes Pharmacy in New Jersey is one place where I can get a custom replacement for a product that would otherwise be harmful to me.

If the subject restriction is implemented, then a safe source of both over-the-counter and prescription medications will be denied to me. More important these sources will be denied to the thousands of other people who have dietary restrictions and allergies.

Please do not implement the subject restriction! Finding effective and safe medication is difficult enough for people such as myself without imposing this restriction!

Thank you for your thoughtful consideration.

Sincerely,

Kathleen P. Mahoney
Laboratory Administrator

Home address:
9 Baldwin Place
Everett MA 02149

98N-1265

C 837